

510(k) Summary

General Information

Classification	Class II
Trade Name	Trellis™ Plus Infusion System
Submitter	Bacchus Vascular, Inc. 3110 Coronado Drive Santa Clara, CA 95054 408-980-8300
Contact	Gregory J. Mathison Vice President, Clinical and Regulatory Affairs, Quality Assurance

Intended Use

The Trellis™ Plus Infusion System is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

Predicate Devices

Trellis Infusion System K013635
Manufactured by Bacchus Vascular, Inc.

Device Description

The Trellis Plus Infusion Catheter enables the physician to isolate a treatment region, infuse a physician-specified fluid, and disperse the fluid by means of oscillation of a Dispersion Wire. The Isolation/Infusion component is a multi-lumen catheter with two compliant balloons at the distal end and infusion holes located between these balloons. When inflated, the compliant balloons isolate a treatment zone to maintain concentration of the infused fluid. The device also has a central through-lumen that is compatible with a 0.035" guidewire. The Dispersion Wire component is a sheathed, shape-set Nitinol cable that provides oscillation when activated. The Dispersion Wire is connected to an integral Oscillation Drive Unit which oscillates the Dispersion Wire up to 25 Hertz within the isolated region to further disperse the infused fluid.

Materials

All materials used in the manufacture of the Trellis Plus are suitable for this use and have been used in numerous previously cleared products.

Testing Summary

The Trellis Plus Infusion System was tested in the same manner as the Trellis Infusion System (K013635). All components, subassemblies, and/or full devices met the required specifications for the completed tests. The Trellis Plus was designed under the Bacchus Quality System which is in compliance with 21CFR§820.30.

Summary of Substantial Equivalence

The Trellis Plus Infusion System is equivalent to the predicate product, the Trellis Infusion System. The indications for use, function, methods of manufacturing, and materials used are substantially equivalent. Bacchus Vascular, Inc. believes the Trellis Plus Infusion System is substantially equivalent to existing legally marketed devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 2002

Bacchus Vascular, Inc
c/o Mr. Gregory J. Mathison
Vice President, Clinical Affairs, Regulatory Affairs, Quality Assurance
3110 Coronado Drive
Santa Clara, CA 95054

Re: K021958
Device Name: Trellis Plus Infusion System
Regulation Number: 21 CFR 870.1210
Regulation Name: Catheter, Continuous Flush
Regulatory Class: Class II (two)
Product Code: 74 KRA
Dated: June 13, 2002
Received: June 14, 2002

Dear Mr. Mathison

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Donna-Bea Tillman", written in a cursive style.

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): This application

Device Name: Trellis Plus Infusion System

Indications for Use: The Trellis™ Plus Infusion System is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

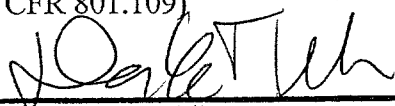
PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR Over-The-Counter Use ☐

(Per 21 CFR 801.109)

(Optional Format 1-2-96)


(Division Sign-Off)
Division of Cardiovascular
and Respiratory Device

510(k) Number K021958

000011

~~Confidential~~